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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/557,519	04/25/2000	Torleif Ove Bjornson	ACBL028.01US	8273

33603 7590 09/11/2003
ACLARA BIOSCIENCES, INC.
1288 PEAR AVENUE
MOUNTAIN VIEW, CA 94043

EXAMINER

STARSLAK, JOHN S

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 09/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.



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7590 06/17/2003

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[REDACTED] EXAMINER

STARSIAK, JOHN S

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

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*Rermailed
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Palo Alto, CA 94306

EXAMINER

STARSIAK, JOHN S

ART UNIT	PAPER NUMBER
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DATE MAILED 04/03/2003

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Remailed
6/17/03*

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Office Action Summary

Application No.	Applicant(s)
09/557,519	Torleif Bjornson et al.
Examiner J. STARSIAK	Group Art Unit 1753

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- Responsive to communication(s) filed on 25 April 2000
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- Claim(s) 1-8 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- Claim(s) 1-8 is/are rejected.
- Claim(s) _____ is/are objected to.
- Claim(s) _____ are subject to restriction or election requirement

Application Papers

- The proposed drawing correction, filed on _____ is approved disapproved.
- The drawing(s) filed on _____ is/are objected to by the Examiner
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- All Some* None of the:
- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____
- Copies of the certified copies of the priority documents have been received
in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____

Attachment(s)

- Information Disclosure Statement(s), PTO-1449, Paper No(s). 4 Interview Summary, PTO-413
- Notice of Reference(s) Cited, PTO-892 Notice of Informal Patent Application, PTO-152
- Notice of Draftsperson's Patent Drawing Review, PTO-948 Other _____

Office Action Summary

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DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites, “each unit comprising a plurality of microfluidic network of reservoirs....each unit having a reservoir positioned in the array in the same format of a source array of at least one of samples and reagents. It is unclear whether the source array is being claimed or not. Similarly, is the “96 well microtiter well [plate]” is being claimed in claim 3. Claim 2 recites “each of the rows of units ...” This recitation does not have proper antecedent basis in claim 1. Claim 4 recites, “said microfluidic units comprising a microfluidic network of *a plurality of reservoirs*wherein *reservoirs for receiving* at least one of samples and reagents are positioned in the array in the same format of *a source array*, wherein said source array is a *microtiter well plate...*” This recitation is indefinite for two reasons. First it is unclear if the “reservoirs for receiving...” correspond to “a plurality of reservoir”. Second it is unclear if a source array, i.e. a microtiter well plate is being claimed. Claim 7 recites, “A microfluidic unit array according to Claim 6, in combination with a plate comprising wells for receiving liquid”.

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First, this recitation fails to recite any structural relationship between the plate/wells and the structure recited in claim 6. Second it is unclear if the plate corresponds to the source array recited in claim 4. Claims 5 and 6 are rejected because they depend on claim 4.

Claim 8 provides for the use of the microfluidic unit assay according to claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 8 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Although the applicant used the Jepson format and use the word “employing” instead of “using” this is a “use” claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Regnier et al in view of Sundberg et al.

Regnier et al teaches [col. 35, lines 53-58]: "The apparatus also may be a chip such as a microchip having multiple parallel channels formed in solid substrates. Such devices allow many separate analyses to be performed in parallel, achieving a high throughput. Referring to FIG. 10, the apparatus 76 comprises multiple capillary channels 58 each have a sample injection zone 52, a buffer reservoir 54, and injection/waste reservoir 66, and a waste reservoir 68. Hence, while Regnier et al general teaches microchip with a plurality of devices, it does not explicitly teach a microchip with 96 devices arranged in a 12 by 8 matrix. Sundberg et al discloses a device for loading samples onto microfluidic apparatus, that includes a plurality of pins 38. Sundberg et al teaches [col. 5, lines 59 to 63]: "The pins may optionally be aligned in an array corresponding to

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at least a portion of a standard microtiter plate, e.g. 12 rows of 8 pins on 9 mm spacings and other liquids with conventional chemical and biological techniques.” Hence, the embodiment of Sundberg et al. comprising 96 pins would be used to simultaneously load samples onto a microchip with 96 devices arranged in 12 by 8 matrix. It would have been obvious to one of ordinary skill in the art at the time of the invention to make the microchip of Regnier et al. with 96 devices arranged in a 12 by 8 matrix because this embodiment corresponds to the standard microtiter plate used in the art as taught by Sundberg et al.

Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Regnier et al. in view of Sundberg et al as applied to claims 1-3 above, and further in view of Soane et al.

Regnier et al. modified in view of Sundberg et al. has all the particulars recited in the above claims except that Regnier et al uses a plate instead of a film to cover the substrate. Soane et al. teaches [col. 5, lines 1-6]: “As the microchannel(s) present on the surface may be open, it may be desirable to separate the internal volume of the channel, and thereby the medium in the channel, from the external environment. In such instances a cover can be employed, which may take the form of a *cover plate or a film cover*.”. It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute a film for the plate of Regnier et al. because substitution of known equivalents in the art is considered to be obvious. Regarding claim 5, Regnier et al. teaches [col. 36, lines 18-22]: “However, the microfluidic device also may be made from a suitable polymeric material such as polystyrene. A microfluidic device made of a

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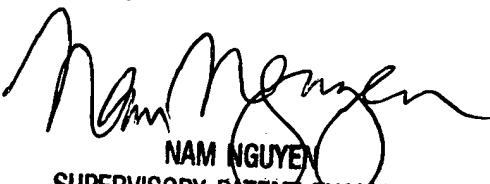
polymeric material permits the use of an inexpensive molded part in a complete system thereby reducing the cost per test."

Conclusion

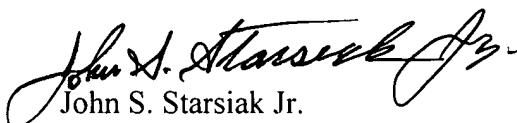
Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Starsiak Jr. whose telephone number is (703) 308-1797. The examiner can normally be reached on Monday to Wednesday from 8:00 AM to 3:30 PM and on Thursday and Friday from 8:00 AM to 12:00 PM..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on (703) 308-3322. The fax phone number for the organization where this application or proceeding is assigned is (703).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



NAM NGUYEN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700



John S. Starsiak Jr.

28 March 2003